Do Not Enter. For discussion only /AS/

FACSIMILE COVER SHEET

Saul Ewing LLP
500 East Pratt Street
Baltimore, MD 21202-3133

	Name	Fax Number	Telephone
To:	571-273-8668	571-273-8668	
From:	Gensits, Sheila M.		(410) 332-8824

Pages (including cover): 13

COMMENT:

Application Serial No. 10/553,098
Docket No. 357074.00009

DRAFT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/553,098	
Filed: November 21, 2006	
Inventor(s): Jeffrey W. Strovel	Confirmation No.: 9106
Attorney Docket No.: 357074.00009	Group Art Unit: 1634
(previously 689290-253)	Examiner: Shaw, Amanda Marie
Title: Determining Cancer-Linked Genes and Therapeutic Targets Using Molecular Cytogenetic Methods	

RESPONSE AFTER FINAL ACTION

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to Office Action dated June 9, 2011 (the "Office Action"), Applicant submits the following remarks. By virtue of a one month extension of time, which is hereby requested, this reply is due by October 9, 2011, and is therefore timely filed. Applicant respectfully requests the Examiner to please reconsider the above-captioned application in light of the following remarks.

DRAFT

In the Claims:

Please amend the claims as follows:

1-4. Canceled)

5. (Currently Amended) A diagnostic assay for cancer or a pre-cancerous condition in a human patient~~mammal~~, comprising:
(a) obtaining a cell or tissue sample from ~~a~~ said patient, wherein said cell or tissue is breast, colon, lung, prostate, ovarian, pancreatic, cervical, or kidney~~mammal suspected of having cancer or a pre-cancerous condition~~said cell or tissue sample being a test sample, and determining for said test sample a test sample gene copy number of a HSPC150 gene;
(b) determining a normal HSPC150 gene copy number in a corresponding cell or tissue from a human~~mammal of the same species~~ not having cancer of the type being diagnosed;
(c) comparing said test sample gene copy number and said normal HSPC150 gene copy number; whereby a higher test sample gene copy number relative to said normal HSPC150 gene copy number indicates the presence of a cancer or pre-cancerous condition and results in a diagnosis of cancer or a pre-cancerous condition in said mammal, wherein said cancer is selected from the group of cancers consisting of breast cancer, colon cancer, lung cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer and kidney cancer.

6-7. (Cancelled).

8. (Previously Presented) The method of claim 5 wherein the HSPC150 gene encodes the same gene product as a polynucleotide of SEQ ID NO: 107.

9. (Withdrawn) A method of inhibiting cancer, or a pre-cancerous condition, in a mammalian cell, comprising contacting said cell with a molecule that inhibits function of a gene of Table 1.

10. (Withdrawn) The method of claim 9 wherein said gene of Table 1 is a gene that encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

11. (Withdrawn) The method of claim 9 wherein said molecule inhibits gene function by binding to said gene.

12. (Withdrawn) The method of claim 9 wherein said molecule inhibits gene function by binding to an RNA encoded by said gene.

13. (Withdrawn) The method of claim 9 wherein said molecule inhibits gene function by binding to polypeptide encoded by said gene.

14. (Withdrawn) The method of claim 9 wherein said molecule is a member selected from an antisense DNA, an antisense RNA, a ribozyme and an siRNA.

15. (Withdrawn) The method of claim 9 wherein said cancer is a member selected from breast cancer, colon cancer, lung cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer and kidney cancer.

16. (Withdrawn) The method of claim 9 wherein said contacting occurs in vivo.

17. (Withdrawn) A method for identifying an agent having therapeutic activity in a human patient in need of said therapeutic activity, comprising:
(a) determining in a sample from a patient the level of a gene product encoded by a gene of Table 1 prior to administering a test compound to said patient;
(b) administering said test compound to said patient;
(c) determining in a sample from said patient the level of a gene product encoded by the same the gene as in step (a)
wherein a decrease in the level of said gene product in step (c) relative to step (a) identifies said test compound as an agent having therapeutic activity.

18. (Withdrawn) The method of claim 17 wherein said therapeutic activity is anticancer activity.

19. (Withdrawn) The method of claim 17 wherein said cancer is a member selected from breast cancer, colon cancer, lung cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer and kidney cancer.

20. (Withdrawn) The method of claim 17 wherein said gene product is an RNA.

21. (Withdrawn) The method of claim 17 wherein said gene product is a polypeptide.

22. (Withdrawn) The method of claim 21 wherein said determination of said polypeptide is a determination of an enzyme activity.

23. (Withdrawn) The method of claim 17 wherein said gene of Table 1 is a gene that encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

24. (Withdrawn) The method of claim 17 wherein said molecule is a member selected from an antisense DNA, an antisense RNA, a ribozyme and an siRNA.

25. (Withdrawn) A method for identifying an antineoplastic agent, comprising:
(a) contacting a test compound with a cell that expresses a gene of Table 1; and
(b) determining a change in gene expression as a result of said contacting;
whereby said change in said gene expression identifies said test compound as an antineoplastic agent.

26-27. (Canceled)

28. (Withdrawn) The method of claim 25 wherein said gene of Table 1 encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

29. (Withdrawn) The method of claim 25 wherein said molecule is a member selected from an antisense DNA, an antisense RNA, ribozyme, an siRNA, a small organic molecule and an antibody.

30. (Withdrawn) A method for determining the cancerous status of a cell, comprising determining elevated expression in said cell of a gene of Table 1 wherein elevated expression of said gene indicates that said cell is cancerous.

31. (Canceled)

32. (Withdrawn) The method of claim 30 wherein said gene of Table 1 encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

33. (Withdrawn) A method for identifying a compound as an anti-neoplastic agent, comprising:
(a) contacting a test compound with a polypeptide encoded by a gene of Table 1,
(b) determining a change in a biological activity of said polypeptide due to said contacting, wherein a change in activity identifies said test compound as an agent having antineoplastic activity.

34. (Withdrawn) The method of claim 33 wherein said gene of Table encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

35. (Canceled)

36. (Withdrawn) The method of claim 33 wherein said biological activity is an enzyme activity.

37-55. (Canceled)

56. (Withdrawn) The method of claim 33 wherein said polypeptide is contained in a cell.

57. (Withdrawn) The method of claim 33 wherein said molecule is a member selected from antisense DNA, an antisense RNA, a ribozyme, an siRNA, a small organic molecule and an antibody.

58. (Withdrawn) The method of claim 57 wherein said antibody is specific for a polypeptide comprising an amino acid sequence of SEQ ID NO: 806 - 854.

59-61. (Canceled)

62. (Withdrawn) A method for treating cancer comprising contacting a cancerous cell with an agent first identified as having gene modulating activity using the method of claim 25, 33, or 58 and in an amount effective to cause a reduction in cancerous activity of said cell.

63-66. (Cancelled)

67. (Withdrawn) A method for treating cancer comprising contacting a cancerous cell with an agent having affinity for an expression product of a gene of Table 1 and in an amount effective to cause a reduction in cancerous activity of said cell.

68. (Withdrawn) The method of claim 67 wherein said expression product is a polypeptide.

69. (Withdrawn) The method of claim 67 wherein said molecule is a member selected from antisense DNA, an antisense RNA, a ribozyme, an siRNA, a small organic molecule and an antibody.

70. (Withdrawn) The method of claim 69 wherein said antibody is specific for a polypeptide comprising an amino acid sequence selected from SEQ ID NO: 806 – 854.

71. (Withdrawn) A method for monitoring the progress of cancer therapy in a patient comprising monitoring in a patient undergoing cancer therapy the expression of a gene of Table 1.

72. (Withdrawn) The method of claim 71 wherein said gene encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

73-74. (Cancelled)

75. (Withdrawn) A method for determining the likelihood of success of cancer therapy in a patient, comprising monitoring in a patient undergoing cancer therapy the expression of a gene of Table 1 wherein a decrease in said expression prior to completion of said cancer therapy is indicative of a likelihood of success of said cancer therapy.

76. (Withdrawn) The method of claim 75 wherein said gene encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

77-78. (Cancelled)

79. (Withdrawn) A method for producing test data with respect to the anti-neoplastic activity of a compound comprising:
(a) identifying a test compound as having anti-neoplastic activity using a method of claim 25;
(b) producing test data with respect to the anti-neoplastic activity of said test compound sufficient to identify the chemical structure of said test compound.

80. (Withdrawn) A method for producing test data with respect to the anti-neoplastic activity of a compound comprising:
(a) identifying a test compound as having anti-neoplastic activity using a method of claim 33;
(b) producing test data with respect to the anti-neoplastic activity of said test compound sufficient to identify the chemical structure of said test compound.

81. (Withdrawn) A method for determining the progress of a treatment for cancer in a patient afflicted therewith, following commencement of a cancer treatment on said patient, comprising:
(a) determining in said patient a change in expression of one or more genes of Table 1; and
(b) determining a change in expression of said gene compared to expression of said one or more determined genes prior to said cancer treatment;
wherein said change in expression indicates progress of said treatment
thereby determining the progress of said treatment.

82. (Withdrawn) The method of claim 81 wherein said change in expression is a decrease in expression and said decrease indicates success of said treatment.

83. (Withdrawn) The method of claim 81 wherein said gene encodes the same gene product as a polynucleotide of SEQ ID NO: 1 - 805 and 855 - 923.

84. (New) A method for diagnosing hepatocellular carcinoma or a precancerous condition related thereto, in a human patient, comprising:
obtaining a liver tissue sample from said patient;
assaying said liver tissue sample to determine the gene copy number of HSPC 150;
diagnosing said human patient with hepatocellular carcinoma or a precancerous condition related thereto, when the gene copy number of HSPC150 is increased in said liver tissue sample relative to the gene copy number of HSPC in a non cancerous liver tissue control sample.

DRAFT

REMARKS

This Reply is in response to the final office action issued on June 9, 2011. Claims 9-25, 28-30, 32-34, 36, 56-58, 62, 67-72, 75,76, and 79-83 are withdrawn from consideration as drawn to non-elected subjection matter. Claim 5 has been amended to better define the invention. Claims 6-7 have been cancelled and new claim 84 added. Thus, the claims presently under consideration are claims 5, 8 and 84. as set forth herein. These claims are supported by the specification as filed, and Applicant believes that no new matter has been added. Applicant respectfully requests that the Examiner reconsider and withdraw the various grounds of rejection of the claims.

I. Rejection under 35 U.S.C. 112, Second Paragraph.

The Examiner objects to claims 5-8 as being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically the Examiner states that the phrase "whereby a higher gene copy number indicates the presence of a cancer or precancerous condition' is indefinite because it is not clear if the higher gene copy number refers to the copy number from the mammal suspected of having cancer or precancerous condition, or the sample from the mammal of the same species not having cancer. Applicant has amended claim 5 herein, thus rendering this rejection moot.

II. Rejection under 35 U.S.C. 112, First Paragraph

The Examiner has rejected Claims 5-8 under 35 U.S.C. 112, first paragraph stating that the specification does not reasonably provide enablement for a method of identifying or

detecting any cancer. Applicant traverses this rejection and respectfully requests the Examiner reconsider the arguments provided in prior responses as well as those set forth below.

Applicant notes that as submitted herein, claim 5 is directed to a human patient. Thus, the claims no longer encompass "a diagnostic assay for any type of mammal (human, cat, whale, bat)". In addition, the cell or tissue sample of claim 5 is now limited to breast, colon, lung, prostate, ovarian, pancreatic, cervical, or kidney. Thus, the claims no longer encompass "a cell or tissue sample wherein the cell or tissue is derived from anywhere (i.e. saliva, hair, breast tissue)". Lastly, Applicant notes that as submitted herein the diagnostic assay is limited to detection of cancer or precancerous condition of the breast, colon, lung, prostate, ovary, pancreas, cervix or kidney. Thus the claims do not encompass "any type of cancer [...] or precancerous condition".

Given these limitations to type of mammal, type of tissue, and type of cancer, Applicant submits that the invention as claimed herein is enabled by the specification as filed.

Applicant has discovered that the genes provided in Table 1 of the application are both over expressed and show an increased copy number when within cancerous or pre-cancerous tissue. Applicant thereby provides a means of distinguishing cancerous/pre-cancerous from non-cancerous tissue.

For example on page 10 lines 23-28, Applicant states: "These genes as identified in Table 1 are amplified in cancer cells relative to non-cancer cells of corresponding tissues, especially breast cancer, colon cancer, lung cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer and kidney cancer." Similarly page 11 lines 26-29 state: "In specific embodiments, the cancer to be diagnosed is one or more of breast cancer, colon cancer, lung cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer and kidney cancer."

Applicant further submits that in view of the nature and breadth of the claimed invention, the state of the prior art, and the level of skill in the art, a person of ordinary skill in the art could have practice the invention as claimed without undue experimentation. Applicant therefore respectfully requests reconsideration of the claims as set forth herein.

III. Rejection under 35 U.S.C. 103

The Examiner has rejected claims 5 and 6 under 35 USC 103 as being unpatentable over Crawley. The Examiner has rejected claim 8 under 35 USC 103 as being unpatentable over Crawley in view of GenBank (Accession No. A1990409). The Examiner states on page 19 that claim 7 is not rejected under 35 USC 103 in view of Crawley.

Applicant has incorporated the elements of clam 7 into independent claim 5, thereby rendering this rejection moot.

Conclusion

In view of the foregoing remarks, Applicant respectfully requests the timely allowance of the pending claims. Should the Examiner believe that any further action is necessary to place this application in better form for allowance, the Examiner is invited to contact Applicant's representative at either the telephone number listed below or Applicant's cell phone 443-831-2937.

Application Serial No. 10/553,098
Docket No. 357074.00009

Applicant hereby petitions for an Extension of Time to reply within the first (1rst) month following the shortened statutory period to respond. The commissioner is authorized to charge any required fees ("small entity" status) to Deposit Account No. 50-4364 (357074.00009)..

Respectfully Submitted,

DRAFT

Dated: ____

Gianna Julian Arnold
Attorney for Applicant, Reg. No.36,358

Saul Ewing LLP
500 E. Pratt Street, 9th Floor
Baltimore, MD 21202
Tel: 410.332.8685
Fax: 410.332.8085
Customer No: 74549